CMS Manual System Department of Health & Human Services

Pub 100-04 Medicare Claims Centers for Medicare &

Medicaid Services

Processing

Transmittal 662

Date: AUGUST 26, 2005 Change Request 4035

SUBJECT: October 2005 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES: This Recurring Update Notification describes changes to the OPPS, to be implemented in the October 2005 update. This notification further describes changes to payment policy and billing procedures under the OPPS.

NEW/REVISED MATERIAL:

EFFECTIVE DATE: October 01, 2005

IMPLEMENTATION DATE: October 03, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R = REVISED, N = NEW, D = DELETED - Only One Per Row.

R/N/D	Chapter / Section / SubSection / Title
N/A	

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

Recurring Notification Form

*Unless otherwise specified, the effective date is the date of service.

Attachment – Recurring Update Notification

Pub. 100-04 Transmittal: 662 Date: August 26, 2005 Change Request 4035

SUBJECT: October 2005 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to the OPPS, to be implemented in the October 2005 update. This notification further describes changes to payment policy and billing procedures under the OPPS. The October 2005 OPPS OCE and OPPS PRICER will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this notification. Unless otherwise noted, all changes addressed in this notification are effective for services furnished on or after October 1, 2005. October 2005 revisions to the OPPS OCE data files, instructions, and specifications are provided in Change Request 4007, 'October 2005 Outpatient Prospective Payment System Code Editor (OPPS OCE) Specifications Version 6.3.'

B. Policy:

1. Expansion of the Device Dependent Edits

Effective April 1, 2005, CMS implemented the first phase of device edits in the OCE. These edits return to providers claims for services in which the provider did not include a code for a major device that is necessary to perform the procedure where is a HCPCS code for the device.

Effective October 1, 2005, CMS is expanding the device edits to apply to more procedure codes for which the use of a device is essential to the performance of the procedure. Refer to Change Request 4017 'Billing for Devices Under the Hospital Outpatient Prospective Payment System (OPPS)'. These edits can be found at http://www.cms.hhs.gov/providers/hopps/default.asp.

These edits have been posted on the CMS website and continuously open to public comment since the issuance of the 2005 OPPS final rule on November 1, 2004. We have incorporated many of the comments we have received into the device edits for implementation on October 1, 2005.

You will note that there are some HCPCS codes for procedures that require a device but for which there are no device edits. This is not an oversight. In some cases, the device codes that exist do not describe all possible devices that could be used in the procedure and, therefore, an edit could return a claim that properly coded the procedure but omitted the device because there is not an appropriate code for the device that was used. In other cases, the procedure is not on the list of procedures that have received adjusted payment and special scrutiny in the past and, therefore, no device editing is being applied at this time. CMS may, in the future, expand the device edits.

Comments or questions about the content of the edits should be directed to Outpatientpps@cms.hhs.gov. The inquirer should identify the writer and the HCPCS code involved and should include rationale for why the commenter believes that the edit of concern should be revised.

Claim specific questions should be directed to the Fiscal Intermediary.

2. No Cost Device Billing Clarification

In Change Request 3915, transmittal 585 dated June 17, 2005, we provided direction regarding how to report devices for which the hospital incurs no cost. That instruction stated that hospitals paid under the OPPS that surgically implant a device furnished at no cost to the hospital shall report a charge of zero for the device, or, if the hospital's billing system requires that a charge be entered, the hospital shall submit a token charge (e.g. \$1.00) on the line with the device code.

Since the FISS system will only accept a zero for the line reporting surgical procedure, hospitals should submit a token charge (e.g. \$1.00) on the line with the device code and not report a zero charge as previously stated.

3. New Service

The following new service is assigned for payment under the OPPS:

HCPCS	Effective Date	SI	APC	Short Descriptor	Long Descriptor	Payment	Minimum Adjusted Copayment
C9725	10/01/05	S	1507	Place endorectal app	Placement of endorectal intracavity	\$550.00	\$110.00
					applicator for high intensity		
					brachytherapy		

4. Payment for New Brachytherapy Sources

Section 621(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established separate payment for brachytherapy devices consisting of a seed or seeds (or radioactive source), based on the hospital's charges for the source(s), adjusted to cost, effective January 1, 2004 through December 31, 2006. CR 3154, issued March 30, 2004, provided instructions regarding this change to billing and payment for brachytherapy sources and identified the applicable codes that became effective for this payment as of January 1, 2004.

The following table lists one new code that may be reported for payment as a brachytherapy source under the OPPS:

HCPCS	Effective	SI	APC	Short	Long Descriptor
	Date			Descriptor	
C2637	10/01/05	Н	2637	Brachytx,	Brachytherapy source,
				Ytterbium-169	Ytterbium-169, per source

5. Drugs and Biologicals

a. Drugs with Payments Based on Average Sales Price (ASP) Effective October 1, 2005

The table below lists the drugs and biologicals whose payments under the OPPS will be established in accordance with the ASP methodology that is used to calculate payment for drugs and biologicals in the physician office setting. In the 2005 OPPS final rule (69 FR 65777), it was stated that payments for drugs and biologicals based on ASP will be updated on a quarterly basis as later quarter ASP submissions become available. In cases where adjustments to payment rates are necessary, we will incorporate changes to the payment rates in an appropriate quarterly release of the OPPS PRICER and we will not be publishing the updated payment rates in the program instructions implementing the associated quarterly update of the OPPS. However, the updated payment rates can be found in the October 2005 update of OPPS Addendum A and Addendum B on the CMS web site.

Single-indication orphan drugs payable under OPPS are also listed below. The methodology used to establish payment rates for these drugs is discussed in the 2005 OPPS final rule (69 FR 65807).

HCPCS	APC	Long Description					
		Human fibroblast derived temporary skin substitute, per					
C9123	9123	247 square centimeters					
C9127	9127	Injection, paclitaxel protein-bound particles, per 1 mg					
C9128	9128	Injection, pegaptamib sodium, per 0.3 mg					
C9129	9129	Injection, Clofarabine, per 1 mg					
		Injection, Perflexane lipid microspheres, per single use					
C9203	9203	vial					
C9205	9205	Injection, Oxaliplatin, per 5 mg					
C9206	9206	Collagen-glycosaminoglycan bilayer matrix, per cm2					
C9211	9211	Injection, Alefacept, for intravenous use per 7.5 mg					
C9212	9212	Injection, Alefacept, for intramuscular use per 7.5 mg					
C9218	9218	Injection, azacitidine, 1 mg					
		Sodium hyaluronate per 30 mg dose, for intra-articular					
C9220	9220	injection					
C9221	9221	Acellular dermal tissue matrix, per 16cm2					
C9222	9222	Decellularized soft tissue scaffold, per 1 cc					
C9224	9224	Injection, Galsulfase, per 5 mg					
		Injection, Fluocinolone acetonide intravitreal implant,					
C9225	9225	per 0.59 mg					
C9226	9226	Injection, Ziconotide for intrathecal infusion, per 5 mcg					
J0128	9216	Abarelix for injectable suspension, per 10 mg					
J0135	1083	Injection, adalimumab, 20 mg					

HCPCS	APC	Long Description				
J0180	9208	Injection, IV, Agalsidase beta, per 1 mg				
J0205	900	Injection, Alglucerase, per 10 units				
J0256	901	Alpha 1 proteinase inhibitor-human, 10 mg				
J0595	703	Injection, Butorphanol tartrate 1 mg				
J0878	9124	Injection, daptomycin per 1 mg				
J1457	1085	Injection, gallium nitrate, 1 mg				
J1785	916	Injection imiglucerase, per unit				
J1931	9209	Injection, laronidase, 0.1 mg				
J2185	729	Injection, meropenem, 100 mg				
J2280	1046	Injection, moxifloxacin 100 mg				
J2355	7011	Oprelvekin injection, 5 mg				
J2357	9300	Injection, omalizumab, per 5 mg				
J2469	9210	Injection, palonosetron HCI, 25 mcg				
J2783	738	Injection, rasburicase, 0.5 mg				
J2794	9125	Injection, risperidone, long acting, 0.5 mg				
		Injection Thyrotropin Alpha, 0.9 mg, provided in 1.1				
J3240	9108	mg vial				
J3411	1049	Injection, Thiamine HCL 100 mg				
J3415	1050	Injection, Pyridoxine HCL 100 mg				
J3465	1052	Injection, voriconazole, 10 mg				
J3486	9204	Injection, Ziprasidone mesylate, per 10 mg				
		Aminolevulinic acid HCL for topical administration,				
J7308	7308	20%, single unit dosage form (354mg)				
J7513	1612	Daclizumab, parenteral, 25 mg				
J7518	9219	Mycophenolic acid, oral, per 180 mg				
		Methacholine chloride administered as inhalation				
J7674	867	solution through a nebulizer, per 1mg				
J8501	868	Aprepitant, oral, 5 mg				
J9010	9110	Alemtuzumab, 10 mg				
J9015	807	Aldesleukin, per single use vial				
J9017	9012	Arsenic trioxide, 1 mg				
J9035	9214	Injection, Bevacizumab, per 10 mg				
J9041	9207	Injection, Bortezomib, 0.1 mg				
J9055	9215	Injection, Cetuximab, per 10 mg				
J9160	1084	Denileukin diftitox, 300 mcg				
J9216	838	Interferon gamma 1-b, 3 million units				
J9300	9004	Gemtuzumab ozogamicin, 5 mg				
J9305	9213	Injection, Pemetrexed, per 10 mg				
Q2019	1615	Injection, Basiliximab, 20 mg				
Q4075	1062	Injection, Acyclovir, 5 mg				
Q4076	1070	Injection, Dopamine HCL, 40 mg				
Q4077	1082	Injection, Treprostinil, 1 mg				
Q4079	9126	Injection, Natalizumab, per 1 mg				

b. Updated Payment Rates for Certain Drugs and Biologicals Effective July 1, 2005 through September 30, 2005

The payment rates for the drugs and biologicals listed below were incorrect in the July 2005 OPPS PRICER. The corrected payment rates will be installed in the October 2005 OPPS PRICER, effective for services furnished on July 1, 2005 through implementation of the October 2005 update.

HCPCS	APC	Short Description	Corrected Payment Rate	Corrected Minimum Adjusted Copayment
C9129	9129	Inj clofarabine	\$29.21	\$5.84
C9211	9211	Inj, alefacept, IV	\$593.60	\$118.72
J0595	0703	Butorphanol tartrate 1 mg	\$0.94	\$0.19
Q4075	1062	Acyclovir, 5 mg	\$0.03	\$0.01

c. Newly-Approved Drugs and Biologicals Eligible for Pass-Through Status

The following drugs and biologicals have been designated as eligible for pass-through status under the OPPS effective October 1, 2005. Payment rates for these items can be found in the October 2005 update of OPPS Addendum A and Addendum B on the CMS web site.

HCPCS	APC	SI	Long Description
C9225	9225	G	Injection,fluocinolone acetonide intravitreal implant, per 0.59 mg
C9226	9226	G	Injection, ziconotide for intrathecal infusion, per 5 mcg

d. Payment for Drugs and Biologicals Recently Approved by the FDA

Transmittal 188 (CR 3287), the Medicare Claims Processing Manual, Pub. 100-04 issued May 28, 2004, explains how hospitals may report new drugs and biologicals after the Food and Drug Administration (FDA) approval but before assignment of product-specific HCPCS codes. The MMA requires, beginning in 2004, that payment for new drugs and biologicals after FDA approval but before assignment of product-specific HCPCS codes be equal to 95 percent of Average Wholesale Price. We are assigning the following product-specific HCPCS code for billing a biological that was approved by the FDA on May 31, 2005. Payment rate for this item can be found in the October 2005 update of OPPS Addendum A and Addendum B on the CMS web site.

HCPCS	SI	APC	Short Descriptor	Long Descriptor	Effective Date
C9224	K	9224	Injection, galsulfase	Injection, galsulfase, per 5 mg	5/31/2005

For claims submitted prior to successful implementation of the October 2005 OPPS OCE, hospitals may bill for this biological using HCPCS code C9399, Unclassified Drug or Biological, in accordance with CR 3287. For claims submitted on or after implementation of the October 2005 OPPS OCE, hospitals should bill for this biological using HCPCS code C9224.

e. Change in the effective date of HCPCS code J8501 (Aprepitant, oral, 5 mg)

In the July 2005 update of the OPPS, we stated that HCPCS code J8501 was approved for pass-through status effective April 6, 2005. However, a national coverage decision for oral aprepitant was announced with an effective date of April 4, 2005. Therefore, the effective date of pass-through status for J8501 has been changed to April 4, 2005. On or after the implementation of the October 2005 OPPS OCE, hospitals may submit claims for oral aprepitant furnished on April 4, 2005 and April 5, 2005.

6. Coverage Determinations

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal intermediaries determine whether a drug, device, procedure, or service meets all program requirements for coverage, for example, that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement "Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply) F R C D Shared System Other										
			R H H I	C a r r i e r	D M E R C		intain M C S	ners	em C W F	Other		
4035.1	FISS shall install the October 2005 OPPS PRICER.					X						
4035.2	Using the October 2005 OPPS PRICER, FISS shall mass adjust payment for lines that 1) have one of the following HCPCS codes and 2) were previously processed through the July 2005 OPPS PRICER. C9129, C9211, J0595, Q4075					X						
4035.3	Using the October 2005 OPPS OCE, FIs shall mass adjust payment for lines that have 1) HCPCS code J8501, 2) date of service April 4, 2005 or April 5, 2005, and 3) were processed prior to installment of the October 2005 OPPS OCE.	X	X									
4035. 4	FIs shall return to providers claims for Injection, galsulfase, per 5 mg billed using HCPCS code C9399 that are submitted after the installation of the October 2005 OPPS OCE.	X	X									

III. PROVIDER EDUCATION

Requirement	Requirements		_			•		indi	icate	es the
Number		F I	R H H I	C a r r i e r	D M E R C		red S intain		em C W F	Other
4035.5	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X							

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: October 1, 2005

Implementation Date: October 3, 2005

Pre-Implementation Contact(s):

Marina Kushnirova

marina.kushnirova@cms.hhs.gov

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Post-Implementation Contact(s): Regional Office

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.

^{*}Unless otherwise specified, the effective date is the date of service.